Attorney Docket # 67,500-353

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re application of: | Wilson, et al. |
| Serial No.: | 09/751,397 |
| Group Art Unit: | 1761 |
| Filed: | January 2, 2001 |
| Examiner: | Tran, Lien Thuy |
| For: | **WAXY WHEAT PRODUCTS AND PROCESSES FOR PRODUCING SAME** |

**DECLARATION UNDER 37 C.F.R. § 1.132**
**SUBMISSION OF SUPPORTING DATA**

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

I, Lori Ann Wilson, hereby state that:

1. I am one of the inventors of the present application and a person of ordinary skill in the art.

2. I received a B.S. in Food Science and Human Nutrition from Michigan State University in 1980. I began working in the Research and Development area at the Kellogg Company in 1980. For the first 16 years I worked in cereals and cereal processing. For the last 7.5 years I have worked in the Quality area of cereals and cereal processing for the Kellogg Company.

3. This Declaration provides evidence that our (i.e., the Applicants') invention is not obvious to a person of ordinary in the art over Alderman (United States Patent No. 2,526,792) in view of Nakamura et al. (Production of waxy (amylose free) wheats, in Mol. Gen. Genet. 248: 253-259 (1995)) and the book Wheat Chemistry and Technology, edited by Y. Pomeranz, 3rd Ed. 1988, pp 10 and 16-17. I am aware of, have read, and understand the cited references.

4. To demonstrate that the whole grain waxy wheat of the present application is different from and not obvious based on Alderman I took two portions of whole grain waxy wheat from the same grain lot and origin. One portion was treated per Example 5 of Alderman as described below, the only example wherein he uses a whole grain in his disclosed process. The other portion was treated as per the present application as described below.

5. In the industry whole grain is defined as intact kernels or fractions thereof that contain the three parts of the whole grain, namely the outer bran, the endosperm, and the germ.

6. To test the Alderman process 15 pounds of the whole grain waxy wheat were combined with 1.31 pounds of sugar, 0.44 pounds of salt, and 5 pounds of water. The mixture was cooked at 15 pounds per square inch of steam for 1 hour and 40 minutes in a rotary cooker at 2.3 rpms. The cooked waxy wheat was then dried at 250° F for approximately 40 to 50 minutes to a moisture of 16.1%. The cooked waxy wheat was then tempered per the Alderman procedure for 24 hours. The cooked and tempered waxy wheat was then run through flaking rollers. Finally, the milled, cooked, waxy wheat was toasted as per Example 5 of Alderman. The resulting product was then tested for a variety parameters related to claim 1 included the amount of whole grain, degree of gelatinization, and storage stability.

7. The other portion of whole grain waxy wheat was treated per the present application. In a first step 23 pounds of the whole grain waxy wheat was placed in a rotary cooker and steamed at 15 pounds per square inch for 15 minutes at 2.3 rpms. As described in the present application, this steaming process serves to inactivate the lipases, which are believed to make cooked whole grain waxy wheat unstable and subject to rancidity. This steaming process also makes the bran layer pliable. The steamed whole grain waxy wheat was then bumped by passing it through rollers set at 300 mm. The bumping of the uncooked waxy wheat creates small fissures in the bran layer, but does not remove any of it. Then 15 pounds of the bumped waxy wheat was mixed with a slurry of 1.31 pounds of sugar, 0.44 pounds of salt, and 3.0 pounds of water. The fissures allow the slurry to penetrate the whole grain during the cooking process. The mixture was cooked in a rotary cooker at 15 pounds per square inch, 2.3 rpms, for 45

minutes. During the cooking process according to the present invention the starches in the whole grain waxy wheat tend to become glue like and hold the outer bran layer onto the whole grain. The cooked whole grain waxy wheat was then dried at 250° F for approximately 20 minutes to a moisture of 16.4%. Next the warm, dried whole grain waxy wheat was roller milled while at a temperature of from 100 to 120° F. The milled grain was cooled and then tempered for 24 hours. In the process of the present invention roller milling the cooked whole grain waxy wheat when it is warm ensures that the starches are above the glass transition state so they are pliable and can be formed without shattering. Finally, the tempered whole grain waxy wheat was toasted as above. The resulting product was then tested for a variety parameters related to claim 1 included the amount of whole grain, degree of gelatinization, and storage stability.

8. The amount of insoluble fiber and the amount of total fiber in each product was measured and compared. The fiber is found in the outer layer of the grain and its level goes down as a grain is converted from a whole grain to a processed grain. Thus, this is a measure of whether each is a "whole grain waxy wheat" as required by claim 1. The product of Alderman had an insoluble fiber level of 6.29 weight % and a total fiber level of 9.99 weight %. By way of contrast, the product as claimed in claim 1 had an insoluble fiber level of 10.14 weight % and a total fiber level of 13.56 weight %. Clearly, the Alderman product is not a whole grain as claimed in claim 1 since it has a lower insoluble and total fiber level compared to the product as claimed in claim 1.

9. The degree of gelatinization can be measured in a number of ways including by measuring water solubility, alkali solubility, and by rapid viscosity analysis. The higher the percentage of water solubility or alkali solubility the greater the degree of gelatinization. The water solubility is in terms of grams per 100 grams in water. The Alderman product had a value of 18 % while the product of the present invention had a value of 23%. The alkali solubility of the Alderman product was 50% while the product of the present invention had a value of 66%. Clearly, by either measurement the Alderman product is not gelatinized throughout as required by claim 1 and as shown in the present invention. The results from the rapid viscosity analysis are attached as Exhibit 1. The viscosity is measured over time as the temperature of the solution is varied. One can see that throughout the entire range of time and temperature the

Alderman product has a much higher viscosity indicating that it is less gelatinized than the product as claimed in claim 1 of the present invention. All of these measures establish that the Alderman product is not gelatinized throughout compared to the product of the present invention and as required by claim 1.

10. The stability of the Alderman product and the product of the present invention were tested using two protocols and measuring the headspace hexanal. This is described in the present specification on page 10, lines 4 – 13 and page 21, line 30 through page 23. In a first protocol the hexanal levels in the headspace were measured after storage for 4 months at a temperature of 70° F and 35% relative humidity representing ambient conditions for 4 months. In a second protocol some of the samples from the first protocol were moved to conditions of 100° F and 70% relative humidity for either 2 or 8 more weeks. Storage under these conditions is used in the industry to simulate longer term storage at ambient conditions in an accelerated fashion. The protocols are well recognized in the food industry. The results are provided in Table 1 below:

TABLE 1

| Condition of storage | Alderman product, headspace hexanal in ppm | Present invention product, headspace hexanal in ppm |
|---|---|---|
| 4 months, 70° F 35% relative humidity | 1.0 | 0.66 |
| 2 weeks, 100° F, 70% relative humidity | 3.58 | 1.28 |
| 8 weeks, 100° F, 70% relative humidity | 6.98 | 3.49 |

The results demonstrate that the Alderman product is not storage stable. After the initial storage of 4 months the Alderman product has significantly more hexanal than the present invention. After the first 2 weeks of accelerated conditions the Alderman product has a hexanal level that is 358% of the measure at 4 months while the present invention is only at 193% of the 4 month measurement. By the end of the 8 weeks of accelerated conditions the Alderman product has a hexanal level of 698% of the 4 month

level and is clearly rancid. Headspace hexanal levels greater than 5 ppm are considered in the industry to represent clear rancidity. By way of contrast, the present invention product is still well below the Alderman product and well below any rancidity threshold.

11. In summary, even if one of ordinary skill were to follow the teachings of the Alderman process using a waxy wheat after reading Nakamura et al. and the book Wheat Chemistry and Technology one could not produce a "Cooked, buoyant, whole grain waxy wheat comprising no more than about 10% amylose starch, and less than 20% by weight protein characterized by being gelatinized throughout and storage stable in the absence of additives that inhibit development of rancidity for at least 6 months." as required by claim 1 of the present application. Alderman alone or in combination with the other cited references does not make the present whole grain waxy wheat product obvious.

12. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information are believed to be true; and further that these statements were made with the knowledge that willful and false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or a patent issued thereon.

Lori Ann Wilson

03/23/2005

Execution Date

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Attorney Docket # 67,500-353

## CERTIFICATE OF MAILING BY "EXPRESS MAIL"

I hereby certify that the enclosed **Declaration Under 37 C.F.R. § 1.132** is being deposited with the United States Postal Service as Express Mail, postage prepaid, in an envelope as "Express Mail Post Office to Addressee", **Mailing Label No.** ########US EV612879574 and addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on **March 23, 2005**.

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# RVA Comparison of Alderman and Wilson/Lai Processes